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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/507,348  | 09/13/2004  | Gioacchino Coppi     | 2541-1025           | 3855             |
| 466   | 7590        | 06/02/2006           | EXAMINER            |                  |
| YOUNG & THOMPSON<br>745 SOUTH 23RD STREET<br>2ND FLOOR<br>ARLINGTON, VA 22202 |             |                      | NGUYEN, TUAN VAN    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3731                |                  |

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/507,348

**Applicant(s)**

COPPI, GIOACCHINO

**Examiner**

Tuan V. Nguyen

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-13 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☒ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Amendment After Non-Final Rejection***

1. According to the Amendment After Non-Final Rejection applicants filed on March 3, 2006, applicant adds claims 10-13. Now, claims 1-13 are pending in this present application.

### ***Response to Amendment***

2. Applicant's arguments filed on March 03, 2006 with respect to claim 1 have been fully considered but they are not persuasive.
3. With respect to arguments regarding claim 1 (currently amended) "None of the references teach a connecting element being used in combination with a stent". Examiner respectfully traverses the applicant's remarks: new limitation "and is used in combination with a stent " is new matter please see rejection in paragraph 4.
4. With respect to arguments regarding "The original claim has been amended so as to clarify that the device being recited is not itself stent but rather is a connecting element which creates a joint between a prosthetic tubular element and a blood vessel ... None of the references teach or suggest such a combination". Examiner respectfully traverses the applicant's remarks: the structure relationship between the tubular element 10 and the prosthesis on which the Applicant relies are not stated in the claims. It is the claims that define the claimed invention, and it is

claims, not specifications that are anticipated or unpatentable. *Constant v. Advanced Mircro-Devices Inc.*, 7 USPQ2d 1064.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitation "is used in combination with a stent" which is new matter.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. **Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Grudem et al (U.S. 6,511,491).**
9. Referring to claims 1-4, Grudem et al disclose (see Fig. 3) a stent device 10, wherein the device comprises an annular element or tubular element having a first portion (20) or first end and a second portion 40 or second end and bears a plurality of outwardly-projecting slender elements (26, 22, 42) arranged in proximity of at least one of the first end and the second end. The slender elements (26, 22) are arranged in proximity of the first end (20) and exhibit a free end (28, 24) facing towards the second end (40). The slender elements (42) are arranged in proximity of the second end (40) and exhibit a free end (44) facing towards the first end (20).
10. As to the recitation that "a device for anastomosis", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
11. **Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleshinski (U.S. 5,755,778).**
12. Referring to claims 1-4, Kleshinski discloses an anastomosis device 10, wherein the device comprises a tubular element having a first collar (14) or first end and a second collar (16) or second end and bears a plurality of outwardly-projecting

slender elements (20) arranged in proximity of at least one of the first end and the second end. The slender elements (20) are arranged in proximity of the first end and exhibit a free end facing towards the second end (16). The slender elements (20) are arranged in proximity of the second end (16) and exhibit a free end facing towards the first end (14).

13. **Claims 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Golden et al (U.S. Pub. No. 2004/0050393).**
14. Referring to claim 11, Golden discloses (see Figs. 1A and 1B) an anastomosis device comprises an annular element or tubular element having a first portion (204) or first end and a second portion (206) or second end and bears a plurality of outwardly-projecting slender elements (210) arranged in proximity of the first end; a tubular prosthesis (G) , wherein the prosthesis is inserted into the tubular element and folded around at least an end of the tubular element with outwardly projecting slender elements so that the outwardly projecting slender elements puncture the prosthesis (see paragraphs [0108], [0109], and [0122]).
15. **Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakura, jr. (U.S. 4,214,587).**
16. Referring to claim 11, Sakura discloses (see Figs. 1-2 and 9) an anastomosis device comprises an annular element or tubular element having a first portion (opposite of reference number 11) or first end and a second portion (11) or second end and bears a plurality of outwardly-projecting slender elements (12) arranged in proximity of the first end; a tubular prosthesis (30), wherein the prosthesis is

inserted into the tubular element and folded around at least an end of the tubular element with outwardly projecting slender elements so that the outwardly projecting slender elements puncture the prosthesis (see col. 3, line 50 to col. 4, line 20 and col. 5, lines 13-20).

***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
19. **Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grudem et al (U.S. 6,511,491) further in view of Killion et al (U.S. 6,159,238).**
20. Referring to claim 5, Grudem et al disclose the invention substantially as claimed except for the tubular element has a longitudinal profile section, which is

truncoconical, and a transversal section, which decreases in a direction going from the first end to the second end. Killion et al disclose an expanded stent device (see Figs. 3 and 6) is of a tapered configuration (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the tapered design, as disclosed by Killion et al, to incorporate into the device, as disclosed by Grudem et al, because this is a matter of design choice since such a design does not solved any stated problem.

21. Referring to claims 6-8, Grudem et al disclose (see Fig. 3) the slender elements are arranged along the circumference of the proximal to the first portion 20 and second portion (40). The slender elements 22, 26 of the first portion (20) or first end are reciprocally distanced at a smaller step with respect to a step at which the slender elements (42) arranged in proximity of the second portion (40) or second end are reciprocally distanced. The slender elements (22, 26) are longer and more prominent than the slender elements (42).
22. Referring to claim 9, it is rejected for the same reason as claim 5.
23. **Claims 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakura, jr. (U.S. 4,214,587) further in view of JP 06,319,755 A.**
24. Referring to claims 10, 12, and 13, Sakura discloses the invention substantially as claimed except for the suture is used for tight around the tubular element. Japanese reference discloses (see Fig. 5) a prosthesis is connected to an anastomosis element by using thread 12 wound around the prosthesis and the



anastomosis (see paragraphs [0022] and [0029]). It would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the thread wound around the prosthesis, as disclosed by Japanese reference, to incorporate into the device, as disclosed by Sakura, because this will improve the security of the connection.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen  
May 18, 2006

  
**ANHTUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
